

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of: Patrick PLE)	Confirmation No. 8039
)	
Application No.: 10/533,931)	Group Art Unit: 1624
)	
Filed: May 4, 2005)	
)	
Patent No.: 7,462,623)	
)	
Issued: December 9, 2008)	Examiner: Truong, Tamthom Ngo
)	
FOR: QUINAZOLINE DERIVATIVES AS SRC)	
TYROSINE KINASE INHIBITORS)	
)	
)	Date: February 9, 2009

REQUEST FOR RECONSIDERATION OF PATENT TERM
ADJUSTMENT UNDER 37 C.F.R. § 1.705(b) and (d) FOR FAILURE TO
ADD FURTHER TERM ADJUSTMENT UNDER § 1.702(b)

This Request for Reconsideration of Patent Term Adjustment is being filed pursuant to 35 U.S.C. § 154(b) and 37 C.F.R. §§ 1.702 - 1.705, and requests that an additional **207** days of patent term adjustment be added to the **551** days of patent term adjustment accorded US Patent 7,462,623 on the first page thereof, for a total of **758** days as detailed below.

This Request for Reconsideration is timely filed under 37 C.F.R. § 1.705(d), being within two month of the December 9, 2008 date on which US Patent 7,462,623 issued. Applicant *agrees* with the US PTO calculation of 553 days of *A Delay* that was stated in the Notice of Allowance. The present request is for reconsideration of the *subsequent* failure of the US PTO to appropriately account for the *B Delay* when calculating the *final* patent term adjustment, which was first indicated in the Issue Notification. Therefore, the issue raised by this Request for Reconsideration could not have been raised prior to payment of the Issue Fee, and is appropriately and timely raised under 37 C.F.R. § 1.705(d) at this time.

Transmitted herewith is deposit account authorization for payment of the \$200 fee set by 37 C.F.R. § 1.18(e). The statement of facts supporting this Request as required by 37 C.F.R. § 1.705(b)(2) is presented below.

STATEMENT OF FACTS UNDER 37 C.F.R. § 705(b)(2)

This Statement of Facts will track the required content for the Statement of Facts as itemized in subparagraphs (i) through (iv) of 37 C.F.R. § 705(b)(2).

(i) The correct patent term adjustment and the basis or bases under § 1.702 for the adjustment; and

(ii) The relevant dates as specified in §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in § 1.703(f) to which the patent is entitled.

The following Table and the accompanying Notes “a” through “e” detail both (i) the correct patent term adjustment and the basis therefore; and (ii) the relevant dates from §§ 1.703(a) - (e) and the adjustment as specified in § 1.703(f) to which the patent is entitled. As used herein, the term “*A Delay*” refers to the days of US PTO delay in excess of the times specified in 37 C.F.R. § 1.702(a); and “*B Delay*” or “*B Period*” refers to the period *after* a date 3-years from application filing until patent grant, as specified in 37 C.F.R. § 1.702(b).

Event	Event Date	A Delays	B Delays	Applicant Delays
Application Filed (§ 371 Date)	4-May-05			
14-Months from § 371 Date	4-Jul-06			
First Action under 35 U.S.C. 132	27-Dec-07	541 ^a		
Reply in Compliance with § 1.113(c)	27-Mar-08			
3-Years from § 371 Date- <i>B Period Begins</i>	4-May-08			
4-months from § 1.113(c) Reply	27-Jul-08			
Notice of Allowance Mailed	8-Aug-08	12 ^b		
3-Months from Notice of Allowance	8-Nov-08			
Issue Fee Paid	10-Nov-08			-2 ^d
Patent Grant - <i>B Period Ends</i>	9-Dec-08		219 ^c	
Totals		553	219	-2
Correct PTA Calculation Per Statute:				
Total <i>A Period</i> Delays		553		
Total <i>B Period</i> Delays		219		
Minus <i>A/B Period</i> Overlap		-12 ^e		
Minus Applicant Delays		-2		
Corrected Patent Term Adjustment		758		
PTA Calculation by US PTO				
Longer of <i>A or B Period</i> Delays		553 ^f		
Minus Applicant Delays		-2		
PTA Indicated on Issued Patent		551		
Additional PTA Per Statutory Calculation over PTA Indicated on Issued Patent		207		

Note a: Under 37 C.F.R. § 1.702(a)(1) and § 1.703(a)(1) there is a **541 day A Delay**, being the number of days in the period beginning on the day after the date that is fourteen months after the date on which the application fulfilled the requirements of 35 U.S.C. 371 (July 4, 2006) and ending on the date of an action under 35 U.S.C. 132 (December 27, 2007).

Note b: Under 37 C.F.R. § 1.702(a)(2) and § 1.703(a)(2) there is **12 day A Delay**, being the number of days in the period beginning on the day after the date that is four months after the date a reply under § 1.111 was filed (July 27, 2008) and ending on the date of mailing of the notice of allowance (August 8, 2008).

Note c: Under 37 C.F.R. § 1.702(b) and § 1.703(b) there is a **219 day B Delay**, being the number of days in the period beginning on the day after the date that is three years after the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application (May 4, 2008) and ending on the date a patent was issued (December 9, 2008) [there are no periods of exclusion under 37 C.F.R. § 1.702(b)(1-5) or § 1.703(b)(1-4) that are here applicable].

Note d: Under 37 C.F.R. § 1.704 (a) and (b) there is a **2 day applicant delay**, being the period of time in excess of three months that was taken from the mailing date of the Notice of Allowance (August 8, 2008) to the actual (but timely) date of US PTO Receipt of the Issue Fee (November 10, 2008; November 8, 2008 being a Saturday).

Note e: Under 37 C.F.R. § 1.703(f) there is a **12 day period of overlap** of periods of delay attributable to the grounds specified in § 1.702, being the **12 day A Delay** (from July 27, 2008 to August 8, 2008) that occurred *during the B Period, which commenced* on the day after the date that is three years after the date on which the national stage commenced under 35 U.S.C. 371(b) (May 4, 2008).

Note f: The US PTO has reinterpreted 35 U.S.C. § 154(b)(1)(B), by “Explanation” published in the June 21, 2004 Federal Register, whereby the US PTO considers the **B Period** to be the entire period of application pendency for purposes of overlap so that applicant gets credit for **A Delay or B Delay**, whichever is longer, but never **A Delay and B Delay**. This interpretation has been rejected by the US District Court for the District of Columbia in *Wyeth v. Dudas*, 88 USPQ2d 1538 (D.D.C. 2008).

Thus, it is respectfully submitted that under the correct interpretation of 35 U.S.C. § 154(b)(1)(B) as confirmed by the District Court in *Wyeth v. Dudas*, there are only 12 days of *A Delay* [July 27, 2008 to August 8, 2008] that occur during (*i.e.*, overlap) the *B Period*, since the *B Period* does not begin until the day *after* the 3-year period from application filing, and runs from then to the date on which the patent issued [here May 4, 2008 to December 9, 2008]. Therefore, as shown on the above Table, Applicant is entitled to a Patent Term Adjustment comprising all 553 days of *A Delay* plus all 219 days of *B Delay* minus the 12 days of *A/B Period* overlap, and minus the 2 days of Applicant delay, or $553 + 219 - 12 - 2 = 758$ days.

(iii) Whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer.

US Patent 7,462,623 is not subject to a terminal disclaimer.

(iv)(A) Any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

The only circumstance during prosecution of the application resulting in the subject patent, which the US PTO considers to be “a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704,” is the 2-day delay occasioned by the timely payment of the Issue Fee on Monday, November 10, 2008, which is 2-days in excess of the date three months from the mailing date of the Notice of Allowance, *i.e.*, Saturday, November 8, 2008, as set forth in Note d to the above Table.

(iv)(B) That there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in § 1.704.

Not applicable - see statement under subparagraph (iv)(A) above.

DISCUSSION

Applicant Agrees With the Preliminary Patent Term Adjustment Determined As of the Mailing Date of the Notice of Allowance

Applicant *agrees* with, and therefore did not contest, the US PTO *preliminary* calculation of 553 days of Patent Term Adjustment as set forth in the Notice of Allowance, which calculation was made before the issue date of the patent was set. This 553 days, *as of the date the Notice of Allowance* was mailed on August 8, 2008, comprised:

- ***541 day A Delay, between July 4, 2006 and December 27, 2007***

37 C.F.R. § 1.702(a)(1) provides that the term of a patent shall be adjusted if issuance of the patent was delayed due to the failure of the US PTO to mail either a notification under 35 U.S.C. § 132 (an Action) or a Notice of Allowance within 14 months after filing of the application (here the § 371 date). The present application has a § 371 date of May 4, 2005, but the first Action was not mailed until December 27, 2007. Thus, pursuant to § 1.703(a)(1), Applicant is entitled to a patent term adjustment for each day of the period between July 4, 2006 (14 months after Applicant's § 371 date) and December 27, 2007, or 541 days.

- ***Plus 12 day A Delay between July 27, 2008 and August 8, 2008***

37 C.F.R. § 1.702(a)(2) provides that the term of a patent shall be adjusted if issuance of the patent was delayed due to the failure of the US PTO to mail an Action or the Notice of Allowance within four months after the filing date of Applicant's preceding reply. Applicant's here-relevant reply was filed on March 27, 2008, but the Notice of Allowance was not mailed until August 8, 2008. Thus, pursuant to § 1.703(a)(2), Applicant is entitled to a further patent term adjustment for each day in the period between July 27, 2008 (four months after the date of the previous reply) and ending August 8, 2008 (the mailing date of the Notice of Allowance), or 12 days.

There were no days of applicant delay under 37 C.F.R. § 1.704 as of the November 8, 2008 mailing date of the Notice of Allowance, and therefore the total period of adjustment under 37 C.F.R. § 1.703(f), *as of the mailing date of the Notice of Allowance* was correctly stated in the Notice of Allowance as being **553 days of US PTO A Delay**.

**Applicant Disagrees With the US PTO
Calculation of the Final Patent Term Adjustment
Indicated in the Issue Notification and Patent Grant**

The Issue Notification mailed November 19, 2008 set December 9, 2008 as the issue date for US Patent 7,462,623, and noted that the Patent Term Adjustment was 551 days. This Patent Term Adjustment of 551 days was also noted on the patent grant. It is respectfully submitted that this *final* Patent Term Adjustment of 551 days is in error.

While the calculation resulting in this 551 day adjustment properly deducts 2 days of applicant delay after the mailing of the Notice of Allowance, it fails to properly account for the 219 days of US PTO *B Delay* accrued during the *B Period* beginning after the 3-year-from-filing date of May 4, 2008 and continuing to the date of patent issue on December 9, 2008. It is understood that this error is the result of the US PTO erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) with respect to the commencement of the *B Period*, whereby the US PTO gives an applicant credit for an *A Delay* or a *B Delay*, whichever is longer, but never gives credit for all or any part of both an *A Delay* and a *B Delay*.

- ***2 day Adjustment for Applicant delay from November 8, 2008 to November 10, 2008***
37 C.F.R. § 1.704(a) provides that the period of adjustment of the term of a patent under § 1.703(a) through (e) shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution (processing or examination) of the application. 37 C.F.R. § 1.704(b) provides that an applicant shall be deemed to have failed to engage in such reasonable efforts for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office, measuring such three-month period from the date the notice or action was mailed. The period of adjustment under § 1.703 is reduced by the number of days beginning on the day after the date that is three months after the date of mailing of the notice or action and ending on the date the reply was filed. The Notice of Allowance was mailed on August 8, 2008, setting the three month date as November 8, 2008, whereas the Issue Fee was timely paid on Monday, November 10, 2008 (November 8 having been a Saturday), whereby the period of applicant delay is 2 days.

- **219 day B Period delay between May 4, 2008 and December 9, 2008**

In addition to the **A Delay** discussed above, 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b) provide for an additional adjustment of the term of the patent of 219 days, which is the number of days attributable to the failure of the US PTO to issue a patent within three years after the filing date (the § 371 date) of the application. Section 1.702(b) provides that the term of a patent shall be adjusted if issuance of the patent was delayed due to the failure of the US PTO to issue the patent within three years after the application filing date (here the § 371 date). The present application has a § 371 date of May 4, 2005 but the subject patent did not grant until December 9, 2008. Thus, pursuant to §1.703(b), Applicant is entitled to a patent term adjustment for each day of the period between May 4, 2008 (the day three years from the filing date of the application) and December 9, 2008, or 219 days **B Delay**.

- **12 day adjustment for A and B Delay overlap**

37 C.F.R. § 1.703(f) provides that the term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of this section, *to the extent that such periods are not overlapping*, less the sum of periods calculated under § 1.704. The **B Period** began after the 3-year-from-filing date of May 4, 2008 and continued to the date of patent issue on December 9, 2008. The **541 day A Delay** extended over the period of July 4, 2006 to December 27, 2007, all *prior to the B Period*, and therefore there is no overlap to be adjusted. However, the **12 day A Delay** extended from July 27, 2008 to August 8, 2008, which falls within the **B Period**. Therefore, pursuant to 37 C.F.R. § 1.703(f), the total Patent Term Adjustment must be adjusted (reduced) by 12 days for this period of overlap.

Again, 37 C.F.R. § 1.703(f) provides that the term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of this section, *to the extent that such periods are not overlapping*, less the sum of periods calculated under § 1.704. Thus, as applicable here, the total period of Patent Term Adjustment, when appropriately calculated, is the total of **553 days A Delay** plus **219 days of B Delay** minus **12 days of A/B Delay overlap** minus **2 days of applicant delay**, for a total Patent Term Adjustment of $553 + 219 - 12 - 2 = 758$ days.

However, because of the erroneous interpretation of 35 U.S.C. § 154(b)(1)(B) by the US PTO, the Patent Term Adjustment accorded this patent in the Issue Notification and on the face of the granted patent is only 551 days. Since the US PTO considered the **B Period** to extend for the full time of application pendency from filing to grant, the US PTO calculation has given Applicant credit for only the longer of the **A** or **B Delay** (thus the 553 day **A Delay**) and has subtracted the 2 days of applicant delay resulting in the 551 days of Patent Term Adjustment accorded this patent.

The District Court in *Wyeth v. Dudas* Has Rejected the US PTO Interpretation for Calculating Patent Term Adjustment in Favor of the Interpretation Used by Applicant Herein

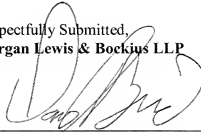
US PTO interpretation of 35 U.S.C. § 154 has been rejected by the United States District Court for the District of Columbia in *Wyeth v. Dudas*, 88 USPQ2d 1538 (D.D.C. 2008). In *Wyeth*, the Court stated that the US PTO interpretation that a period of "B delay" always overlaps with any periods of "A delay" for purposes of applying 35 U.S.C. § 154(b)(2)(A) cannot be squared with the actual language of the statute. *Wyeth*, 88 USPQ2d at 1540. Instead, the court stated that for purposes of 35 U.S.C. § 154(b)(2)(A), a period of delay due to the US PTO failure to issue a patent within three years [the **B Period**] does not begin until *after* three years from the filing date of an application.

Therefore, according to both the clear wording of 35 U.S.C. § 154 and the *Wyeth* decision, the **B Delay** period in the present application started on May 4, 2008, and not on the May 4, 2005 § 371 date. Because only 12 days of **A Delay** overlap with the **B Period**, there are only 12 days to be excluded for overlap (and the 2 days already excluded for applicant delay) from the determination of patent term under 35 U.S.C. § 154(b)(2)(A).

Therefore, Applicant respectfully requests that US Patent 7,462,623 be accorded an additional 207 days (219 days - 12 days for overlap) of Patent Term Adjustment pursuant to 37 C.F.R. § 1.702(b) for the period of **B Delay** in addition to the 551 days of Patent Term Adjustment already accorded this patent in the Issue Notification and patent grant, for a total Patent Term Adjustment pursuant to 37 C.F.R. § 1.703(f) of **758 days**.

The Director is hereby authorized by this paper to charge any additional fees which may be required by reason of this Request for Reconsideration, or credit any overpayment to Deposit Account 50-0310.

Respectfully Submitted,
Morgan Lewis & Bockius LLP



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